

Remarks/Arguments:

Applicant acknowledges the Office Action has deemed the restriction requirement proper and made final. Applicant respectfully requests reconsideration of the restriction requirement for the reason that as drafted, the amended claims directed to combination of the anti-reflux valve and the implantation tool specifically require both the tool and the valve. With respect to the election of species requirement, Applicant respectfully requests that upon allowance of a generic claim, Applicant be allowed to rejoin claims to non-elected species as well as elected species.

By this amendment, claims 10-12 have been cancelled. Claims 1-9, 13-63 are pending in the application. Claims 13, 20, 21, 27, 38 and 44 have been amended. Claims 15, 21-23, 25, 29-55, and 57-63 have been withdrawn from consideration by the examiner. Applicant notes that the amendment to Claim 21 corrects a typographical error and makes claims 21-23 dependent from elected Claim 18 in which it finds proper antecedent basis for the base and tip of the spikes, rather than non-elected Claim 10, now cancelled. Claims 8, 13-14, 18, 24, 27-28, and 56 have been rejected. Claims 1-7, and 9 have been allowed by the Examiner. Claims 16-17, 19-20, and 26 were indicated as allowable, but were objected to.

Amendments to the Claims

Claim 13 has been amended for the purpose of improved clarity, and does not alter the scope or meaning of the claims as originally drafted. Claims 20-21 have been amended to properly depend from Claim 18, which in turn depends from currently amended Claim 13. Additionally, Claim 21 has been amended to correct a typographical error as it should depend from Claim 18, and not Claim 10 as written. Claim 27 has been amended for the purpose of improved clarity, and does not alter the scope or meaning of the claim as originally drafted.

Claim 38 has been amended for the purpose of improved clarity by positively claiming the anti-reflux valve prosthesis of Claim 13. Claim 44 has been amended for the purpose of improved clarity, and does not alter the scope or meaning of the claims as originally drafted. These amendment add no new matter.

Rejection Under 35 U.S.C. § 101

The Office Action has rejected Claim 8 under 35 U.S.C. §101 as being directed to non-statutory subject matter by positively claiming the patient. However, Claim 8 does not claim the patient or the esophagus of a patient. Claim 8 is directed to the anti-reflux valve of Claim 1 in which the valve is implanted in a specific location, namely in the esophagus of a patient having a gastroesophageal reflux disease, and neither directly or indirectly claims the patient. Nor is the implantation of the valve limited to the esophagus of a human patient. The valve can be implanted in the esophagus of a veterinary patient, i.e. an animal. Applicant is unaware of any case or rule that specifically prohibits the use of the word "patient" in the claim when it is the apparatus and not the patient being claimed. Therefore, because claim 8 does not claim the patient and is instead directed to statutory subject matter, reconsideration of the rejection and allowance of the claim is respectfully requested.

Furthermore, even if a "patient" were claimed, allowance of the claim is proper. A patent recently issued in which the body of a living creature was claimed as a part of an apparatus. In U.S. Pat. No. 6,754,472 to Williams, issued on June 22, 2004 and assigned to Microsoft, Claim 1 states in part, "A network of devices comprising:... a body of a living creature for coupling the first device to the second device..." Thus, if the body of a living creature is considered patentable subject matter of an apparatus claim, then a valve implanted in the esophagus of a

patient should also be considered allowable subject matter. Reconsideration of the rejection and allowance of Claim 8 is respectfully requested.

Rejection Under 35 U.S.C. § 102

Claims 13-14, 18, 24, 27-28, and 56 are rejected under 35 U.S.C. §102(e) as being anticipated by Taylor (U.S. Pat. No. 6,558,429) and Bessler et al. (U.S. Pat. No. 5,855,601). The Applicant has considered the rejections in view of the Examiner's comments and respectfully submits that neither Taylor '429 nor Bessler '601 anticipate the present claims, and thus the claims are allowable.

The law of anticipation requires that a single art reference teach, expressly or inherently, every limitation of the rejected claim. *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998). The Applicant respectfully submits that Taylor '429 and Bessler '601 each fail to anticipate the present claims because they fail to teach every limitation of the present invention. Specifically, Taylor '429 fails to teach retractable spikes spaced along the circumference of the annular body, and Bessler '601 fails to teach a perorally insertable device and fails to teach retractable spikes along the annular body.

Referring initially to Claim 13, Taylor '429 fails to teach retractable spikes spaced along the circumference of the annular body. The spikes are described in the specification of Taylor '429 as being "essentially straight and project orthogonally from the ring." See col. 6, lines 59-63. Implantation of the anti-reflux valve disclosed in Taylor '429 is disclosed at col. 7, lines 10-32, and FIGS. 6A – 6E, and involves the bending of the annular ring to fit the prosthesis in the implantation tool. As shown in the figures and disclosed in the specification, the spikes mounted on the Taylor '429 anti-reflux valve project outward from the ring. There is no teaching of

retractable spikes, as the spikes are fully extended outward from the annular ring at all times, and there are no means for retracting the spikes disclosed or suggested therein. The spikes of the present claim however are selectively retractable between a deployed and a retracted position, thereby facilitating peroral implantation and removal of the anti-reflux valve. See page 17, lines 2-4; page 19, line 28 to page 20, line 1; page 20, lines 20-24; and page 21, lines 22-28; describing the retraction and deployment of the spikes. Taylor '429 does not disclose the retractable spikes as claimed and implantation is effected in one embodiment by compressing the ring without any retraction of the spikes; and thus Claim 13 is not anticipated and should be allowed. Claims 14, 18, 21-24, 27-28, and 56 all depend from Claim 13 and should be allowed as depending from an allowable claim.

Similarly, Bessler '601 fails to teach each element of Claim 13. Specifically, Bessler fails to teach a perorally insertable anti-reflux device, and also fails to teach the retractable spikes along the circumference of the annular body. Bessler '601 discloses a heart valve for percutaneous and transluminal implantation. (See col. 4, lines 53-56). The anti-reflux valve of Claim 13, as claimed, is "for peroral implantation in an esophagus." By definition, peroral implantation is a non-invasive procedure. The Bessler heart valve requires an invasive procedure for implantation, whereas the anti-reflux valve of the present claims does not. Furthermore, Bessler '601 does not disclose retractable spikes spaced along the circumference of the annular body, as claimed in Claim 13. Bessler et al. disclose a "plurality of barbs for holding the valve in place once it has been appropriately positioned." (See col. 5, line 67 to col. 6, lines 1-2). Implantation of the device, (see col. 7, lines 25-67, and specifically lines 50-67), is accomplished by feeding through the blood vessel with a flexible catheter. The Bessler heart valve is affixed to the wall of the vessel by expanding the valve and giving a slight pull to set the barbs. (See col. 7,

lines 50-53). Bessler '601 does not teach barbs which are retractable, does not teach a retracted and a deployed spike position, does not teach a perorally implanted valve, and thus, does not anticipate the present claim. Claim 13 should therefore be allowed. Claims 14, 18, 21-24, 27, 28 and 56 all depend from Claim 13, and should be allowed as depending from an allowable claim.

Neither Taylor '429 nor Bessler '601 disclose any motivation or guidance, either singly or collectively, teaching or suggesting any modification to bridge the gap with the claimed invention. Thus, rejection of Claim 13 for obviousness under 35 U.S.C. § 103(a) would likewise be improper.

Referring to Claims 21-23, both Taylor '429 and Bessler '601 fail to teach retractable spikes that are bendable at the base between a retracted and deployed alignment. At column 6, lines 59-63, Taylor '429 discloses spikes that are "essentially straight and project orthogonal from the ring." There is no teaching or suggestion in Taylor '429 of spikes that are bendable between a retracted and deployed alignment, as claimed in Claim 21. Similarly, Bessler '601 fails to teach spikes that are bendable between a retracted and deployed alignment. At column 5, line 67 to column 6, line 2, Bessler discloses a plurality of barbs on the valve, but does not teach or suggest spikes which are bendable at the base between a retracted and deployed position. Because Taylor '429 and Bessler '601 do not teach or suggest spikes which are bendable at the base between a retracted and a deployed position, rejection is improper and should be withdrawn. Allowance of Claims 21-23 is respectfully requested.

Referring to Claims 27 and 28, Taylor '429 and Bessler '601 fail to teach the use of a valve with retractable spikes to relieve Gastroesophageal reflux disease symptoms, or the use of the valve when the patient does not suffer from esophageal cancer. Typically, the decision to implant an anti-reflux valve is not taken lightly, due to the fact that invasive surgery is necessary

for either the implantation and/or extraction of the valve. Thus, implantation of the valve is typically reserved for patients with the most severe symptoms, such as for example, a patient with esophageal cancer. Taylor '429 teaches peroral implantation of an anti-reflux prosthesis, but does not teach the peroral extraction of the device, and Bessler '601 does not teach or suggest a method for peroral implantation or extraction of the anti-reflux valve. Because of the retractable spikes of the anti-reflux valve of Claims 27 and 28, it can be perorally implanted and extracted, without the need for invasive surgery. The valve of the present claim is therefore an option for use in treated less severe symptoms than previously possible. Thus, because Taylor '429 and Bessler '601 fail to teach or suggest the use of the a valve with retractable spikes to relieve symptoms of Gastroesophageal reflux disease or to treat a patient not suffering from esophageal cancer, rejection of Claims 27 and 28 is improper and should be withdrawn. Claims 27 and 28 should therefore be allowed.

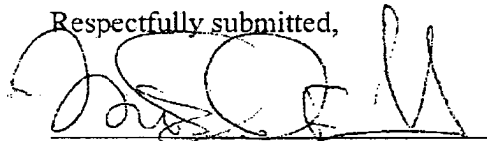
Objections

Claims 16-17, 19-20, and 26 are objected to as depending from a rejected base claim. Specifically, each claim depends from Claim 13, which was rejected in the Office Action as being anticipated under 35 U.S.C. §102 by Taylor '429 and Bessler '601. However, based upon the amendments to the claims and arguments presented in this response, amended Claim 13 should be allowed. Additionally, amended Claim 21, and Claims 22-23 depending therefrom, now depend from Claim 13 and should be allowed. Applicant reserves the right to amend Claims 16-17, 19-23, and 26 to include all of the limitations of the base claim and any intervening claims if the Examiner maintains the rejection of Claim 13.

The prior art references cited by the Office Action fail to disclose or suggest every limitation of the rejected claims. Rejection is therefore improper and withdrawal is respectfully requested. Applicant respectfully requests further examination of the application and upon allowance of a generic claim with respect to the elected species, examination of all claims with respect to the non-elected species as well. Thus, Claim 15 should be rejoined and allowed as depending from an allowable base claim. Further, the subcombination/combination and/or method of using Claims 29-55 and 57-63 should also be joined/rejoined as depending from or incorporating the allowable subject matter of Claim 13 and are properly linked to an allowable claim, and no searching is necessary. See MPEP 821.04. Allowance of all claims is respectfully requested.

Applicant does not believe any fees are due at this time, however the Commissioner is authorized to charge any fees associated with this communication to deposit account 501285. If the Examiner has any questions or comments regarding this communication, the undersigned can be contacted to expedite the resolution of this application.

Respectfully submitted,



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